VERMONT

Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
May 19, 2015

Board Members:
Present:

	Mark Pasanen, MD	James Marmar, RPh
Janet Farina, RPh	Michael Biddle, PharmD	Joseph Lasek, MD, Chair

Absent:
Jaskanwar Batra, MD

Staff:

Michael Ouellette, RPh, GHS/Emdeon	Laureen Biczak,DO, GHS/Emdeon	Jason Pope, DVHA
Thomas Simpatico,MD, DVHA	Mary Beth Bizzari, RPh, DVHA	Stacey Baker, DVHA
Nancy Hogue, PharmD, DVHA	Carrie Germaine, DVHA	Scott Strenio, DVHA

Guests:

Rita Baglini, APS Health Care	Kristen Bruno-Doherty, Astrazeneca	Darren Keegan, Allergan/Actavis
Cara Braun, Lilly	Thomas Currier, Purdue	Marid Carnovale, Novartis
Alicia Teitsma, AstraZeneca	Jennifer Palow, CSG	Scott Williams, J&J
Thomas Algozzine, Novartis	Denman Adam, GSK	Lauren Novakowski, Amgen
Christine Dube, MedImmune	Andrea Traina, AstraZeneca	

Joseph Lasek, MD, Chair, called the meeting to order at 6:30 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:00 until 6:30 p.m.

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The April meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Updates: Nancy Hogue, PharmD, DVHA

- Updated the board that two new members will be joining the Board in June.

4. Medical Director Update: Scott Strenio, MD, DVHA

- No clinical program update.

5. Follow-up Items from Previous Meetings: Mike Ouellette, RPh, GHS/Emdeon & Laureen Biczak, DO, GHS/Emdeon

a) High dose/Long term use in individual patients on diazepam

- GHS/Emdeon presented information in the form of charts showing a variety of different parameters describing the use of diazepam including the proportion of use of the different strengths of diazepam, number of patients concurrently on pain medications with diazepam, percent of patients on non-benzodiazepine sleep agents with diazepam, patients on over 40mg daily, and over 4 tablets daily.

Recommendation: Apply quantity limits of 4 per day across all strengths. Perform a retro-DUR analysis of all VT Medicaid members currently taking multiple benzodiazepines. Request that the Medical Director review all prior authorizations requesting >4 per day for clinical appropriateness. GHS and DVHA will work out how to technically handle prescriptions that are written for alcohol withdrawal, which generally involve a larger number of tablets over a short period of time (2-3 days).

Board Decision: The Board unanimously approved the above recommendation.

b) Amiodarone DDI recommendations

- Due to the long half-life of oral amiodarone, GHS recommended a look back period of 3-6 months for drugs with a high potential of serious toxicity if used with or shortly after amiodarone is discontinued. It was noted that commonly relied upon tools, DDI checkers at pharmacies, EMRs and handheld devices will NOT catch drugs that were given in the past.

Recommendation: When the medications from the "high risk" lists are NEWLY prescribed, a look back period of 90 days will be done to check for amiodarone oral therapy. A hard stop edit requiring prior authorization would be placed if the potential for a severe DDI is found. A one-time data analysis will be done looking at ALL who have been on amiodarone for > 1 dose in the last 6 months (12/1/2014-6/1/2015) to evaluate if any of the high risk DDIs have occurred recently.

Board Decision: Board recommended extending the look-back to 120 days. Otherwise accepted the above recommendations

c) 2015 Retro DUR Initiatives

- Reviewed the Initiatives that were presented at the April DUR meeting to be able to gauge the Committee's interest in these or other topics and to set the schedule for Retro DUR activities for the upcoming year. The Committee expressed interest in the following topics and recommended that these be considered: benzodiazepine when co-

prescribed with opioids or stimulants, use of benzodiazepines in the elderly population, appropriate use of controller medication in asthma patients and hepatitis C adherence.

Recommendation: GHS will take the board's feedback and set a schedule to provide more detail with each intervention.

6. Retro DUR/DUR:

- None at this time.

7. Clinical Update: Drug Reviews:

Abbreviated new Drug Reviews

- None at this time.

Full New Drug Reviews: Mike Ouellette, RPh, GHS/Emdeon & Laureen Biczak, DO, GHS/Emdeon

a) Akynzeo® (netupitant & palonosetron combination)
- Will be included in the Antiemetic therapeutic class review (TCR)

Recommendation: PDL placement and criteria will be recommended when Antiemetic TCR is reviewed.

Public Comment: No public comment.

Board Decision: Defer decision to occur with the class review.

b) Auryxia® (ferric citrate)
- For the control of serum phosphorus levels in patients with chronic kidney disease on dialysis. This is a pregnancy category B medication. The recommended dosage is 2 tablets TID with meals, with a maximum dose of 12 tablets/day. The most commonly reported adverse events included diarrhea, nausea, and constipation. Ferric citrate, the active ingredient in Auryxia®, is a phosphate binder. It binds to dietary phosphate in the GI tract and precipitates as ferric phosphate.

Recommendation: The recommendation is to add Auryxia to the non-preferred side of the PDL with a quantity limit of 12 per day.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) Esbriet® (pirfenidone)
- For the treatment of idiopathic pulmonary fibrosis (IPF). This is a pregnancy category C medication. The recommended dosage is 801mg TID with food. Significant for both drugs in this category is that smoking changes the exposure to the drugs. In the case of Esbriet®, there is a 46% decrease in the area under the curve with smokers. Both drugs in this category were studied against placebo and were not compared to each other. In

addtition, they were both studied in people with a forced vital capacity (FVC) of greater than 50%, which is classified as mild to moderate IPF. This is important to consider when we look at the criteria. The most frequently reported adverse events included nausea, rash, and abdominal pain. There is currently no cure for IPF; however, supportive care plays a vital role, and this includes supplemental oxygen when needed, education, pulmonary rehabilitation, and seasonal influenza vaccination. Smoking should be avoided with Esbriet® use. Esbriet® is now one of two FDA approved medications in the United States that has data which demonstrates slowing of disease progression.

Recommendation: The recommendation is to add Esbriet to the non-preferred side of the PDL with a quantity limit of 270 tabs/month. Clinical criteria:

- ALL of the following:
  - Age ≥ 18.
  - Diagnosis of idiopathic pulmonary fibrosis (IPF-ICD-9 Code 516.31 or ICD-10 Code J84.112) as well as exclusion of other known causes of Interstitial Lung Disease.
  - May not be used in combination with OFEV® or Esbriet® respectively.
  - The prescriber is a pulmonologist.
  - Clinical documentation that the member is a non-smoker or has not smoked in 6 weeks.
  - FVC ≥ 50% of predicted.

- AND one of the following

  - High-resolution computed tomography (HRCT) revealing IPF or probable IPF.
  - Surgical lung biopsy consistent with IPF or probable IPF.

Reauthorization criteria

- Documentation the patient is receiving clinical benefit to Esbriet® or OFEV ® therapy as evidenced by < 10% decline in percent predicted FVC or < 200 mL decrease in FVC.

AND

- There is clinical documentation that the member has remained tobacco-free.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) Mircera® (methoxy polyethylene glycol-epoetin beta)

- Will be included in the Anemia: Hematopoietic/Erythropoietic Agents TCR.

Recommendation: PDL placement and criteria will be recommended when the Anemia: Hematopoietic/Erythropoietic Agents TCR is reviewed.

Public Comment: No public comment.

Board Decision: Defer decision to occur with the class review.

e) Ofev® (nintedanib)

- Treatment of idiopathic pulmonary fibrosis. Ofev® is a kinase inhibitor. This is a pregnancy category D medication. The recommended dose is 150mg BID with food (capsules should not be chewed or crushed). The most frequently reported adverse events included diarrhea, nausea, abdominal pain, and vomiting. Current studies of Ofev® did not demonstrate a mortality benefit but slowing of disease progression in those with mild to moderate desease. This drug also has a 21% decreased exposure in patients who smoke.

Recommendation: The recommendation is to add Ofev® to the non-preferred side of the PDL with a quantity limit of 60 tabs/month. Clinical criteria: same as Esbriet®.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

f) Plegridy® (peginterferon beta-1a)

- Indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). This is a pregnancy category C medication. Plegridy can be given every 14 days, it is given less frequently than other interferons used for MS. The most frequently reported adverse events included headache (11%), nausea (3%), vomiting (3%), and myalgia. Plegridy® was assessed in a randomized, double-blind, placebo-controlled study. There were no active-comparator studies found.

Recommendation: The recommendation is to add Plegridy® to the non-preferred side of the PDL with the following criteria:

- Age ≥18 years.
- Diagnosis of relapsing form of Multiple Sclerosis.
- Documented side effect, allergy, treatment failure or contraindication to at least three preferred drugs including at least one preferred form of interferon.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

g) Trulicity® (dulaglutide)

- Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 Diabetes Mellitus (DM). Trulicity® is not recommended to be used as a first-line treatment for those who have inadequate glycemic control on diet and exercise. It should not be used in those with type 1 DM or for the treatment of diabetic ketoacidosis; it is not a substitute for insulin. The concurrent use with basal insulin has not been studied. Trulicity® has not been studied in those with a history of pancreatitis; thus, it is recommended to consider other antidiabetic therapies in this population. This is a pregnancy category C medication. The medication is administered weekly. The most frequently reported adverse events included nausea, diarrhea, vomiting, abdominal pain. Studies were discussed that compared Trulicity® to several other therapies both as monotherapy and as add-on therapy to other drugs.

Recommendation: The recommendation is to add Trulicity to the non-preferred side of the PDL.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

h) Zavesca® (miglustat)

- Indicated as monotherapy for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g. due to allergy, hypersensitivity, or poor venous access). Take 1 capsule TID at regular intervals. The most frequently reported adverse events included diarrhea, abdominal pain, flatulence, and constipation. There were two open-label, uncontrolled trials and one randomized, open-label, active-controlled trial to assess the safety and efficacy of Zavesca®.

Recommendation: The recommendation is to add Zavesca to the non-preferred side of the PDL.
Clinical criteria:

- For patients for whom enzyme replacement therapy is not a therapeutic option (e.g. due to allergy, hypersensitivity, or poor venous access).
- Age ≥ 18 years.
- Quantity Limit=3 capsules/day
- Additional changes to the criteria recommended for the category included:
  - Moving Elelyso® to the preferred side of the PDL with clinical criteria.
  - Cerezyme®/Vpriv ®additional criteria:
    - Failure, intolerance or other contraindication to enzyme replacement therapy with Elelyso®.
  - Adding additional criteria to Cerdelga®
    - Dose max: 84 mg twice/day if EM or IM
    - Dose max: 84 mg/day if PM
    - Not indicated for URM
    - Case by case determination if CYP2D6 cannot be determined.
- The following age limits were added as well
  - Elelyso®, Vpriv: ® ≥ 4 years
  - Cerezyme®: ≥ 2 years
  - Cerdelga®, Zavesca®: ≥ 18 years

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

i) Xigduo XR® (dapagliflozin &metformin ER)

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 Diabetes Mellitus when treatment with both dapagliflozin and metformin is appropriate. This is a pregnancy category C medication. Recommended dose is one tablet QD with

max dose 10/2000mg. The most frequently reported adverse events included female genital mycotic infections, nasopharyngitis, urinary tract infections, and diarrhea. Of note, at least one noted reference source recommends against routine use of SGLT-2 inhibitors due to a lack of long-term efficacy and safety data.

Recommendation: The recommendation is to add Xigduo XR® to the non-preferred side of the PDL with quantity limits of 5/1000mg: 2/day, all others: 1/day.

Public Comment: Andrea Traina, AstraZeneca : Highlighted some of the attributes of Xigduo XR®.

Board Decision: The Board unanimously approved the above recommendation.

8. Therapeutic Drug Classes- Periodic Review: Mike Ouellette, RPh, GHS/Emdeon and Laureen Biczak, DO, GHS/Emdeon

a) Analgesics/Anesthetics, Topical

- No significant new studies and no new agents.
- No significant clinical or fiscal changes to this category since the last review.

Recommendation: Keep current criteria, drugs that are no longer available to be removed.

Board Decision: The Board unanimously approved the above recommendation.

b) Anemia: Hematopoietic/Erythropoietic Agents

- Current guidelines are fairly clear as to the appropriate dosing of these agents
- No studies suggest that one agent is safer or more effective than the others
- Mircera® is a new drug in this category that may need to be given less frequently. There is no data that it is safer or more effective that the currently preferred agents.

Recommendation: The recommendation is to maintain the current category as configured on the PDL and to add Mircera® to the non-preferred side of the PDL with clinical criteria:

- The diagnosis or indication for the requested medication is anemia due to chronic kidney disease/renal failure AND
  - Hemoglobin level at initiation of therapy is <10g/dl

OR

- For patients currently maintained on therapy, hemoglobin level is ≤11 g/dL in dialysis patients with chronic kidney disease, ≤10 g/dL in non-dialysis patients with chronic kidney disease, or ≤12 g/dL in patients treated for other indications

AND

- The patient has had a documented side-effect, allergy, or treatment failure to both Aranesp® and Procrit®

Board Decision: The Board unanimously approved the above recommendation.

c) Anti-emetics

- This category also has very well established and accepted guidelines for the use of these agents.
- Triple therapy with a 5-HT3 antagonist, an neurokinin 1 (NK1) antagonist and dexamethasone is recommended for highly emetogentic chemotherapy with a preference for IV palonosetron for moderate-high risk IV chemotherapy.
- No single 5-HT3 anatagonist is recommended over the others other than that setting.
- Akynzeo® is a new drug in this category that is a combination of a 5-HT3 antagonist and an NK1 antagonist; it was studied only against a 5-HT3 antagonist treatment.
- There were not other significant clinical changes in this category.

Recommendation: The recommendation is to remove drugs that are no longer available and to maintain other current clinical criteria and to add Akynzeo® to the non-preferred side of the PDL with the following clinical criteria:

- The patient has a diagnosis of nausea and vomiting associated with cancer chemotherapy AND
- The patient has a documented side effect, allergy, or treatment failure of a regimen consisting of a 5-HT3 antagonist, an NK1 antagonist, and dexamethasone.

Board Decision: The Board unanimously approved the above recommendation.

d) Antifungals, Topical & Onychomycosis Agents

- There is no new information in this clinical area other than the new drugs which were reviewed at recent Committee meetings.
- A review of utilization suggests that there is a good mix of clinically effective and cost-effective products in a variety of forms. No change in the criteria is recommended other then the removal of drugs that are no longer available.

Recommendation: The recommendation is to keep the current critiera with the removal of the drugs that are no longer available.

Board Decision: The Board unanimously approved the above recommendation.

e) Dermatological Agents-Immunomodulators

- There is no new significant clinical or cost information in this category and no new products.

Recommendation: The recommendation is to keep the current critiera.

Board Decision: The Board unanimously approved the above recommendation.

f) NSAIDs & COX-2 Inhibitors

- There is no new significant clinical information in this category. This is a category for which is appropriate to have numerous options available. The highlight in the category is the new availability of the generic for Celebrex®.
- There was some discussion around the varied pricing of the generics, some of which are authorized generics. There would be some cost savings to the State if some of the generics were preferred. The pharmacists indicated that it would be helpful to have more than a single product to choose from.

Recommendation: The recommendation is to add the more cost effective NDCs of celecoxib to the preferred side of the PDL. Both brand and generics still require a clinical PA. GHS will create custom messaging via POS to indentify the cost-effective products for pharmacies.

Board Decision: The Board unanimously approved the above recommendation.

g) Scabicides & Pediculicides

- No significant new clinical information.
- The current criteria of requiring two failed treatments of permethrin products before allowing a second line agent(Natroba® at present) makes clinical and fiscal sense and is working well.

Recommendation: The recommendation is to keep the current critiera with the removal of the drugs that are no longer available.

Board Decision: The Board unanimously approved the above recommendations.

h) Skeletal Muscle Relaxants

- No new significant clinical information or new studies

Recommendation: The recommendation is to keep the current critiera with the removal of the drugs that are no longer available. Also, recommended to change the category name to Muscle Relaxants, Skeletal.

- A board member recommended that cyclobenzaprine be moved to the non- preferred side of the PDL due to concerns about abuse potential and drug to drug interactions. After discussion from the board, it was recommended that the current PDL remain unchanged, but that GHS will look into the potential safety concerns as a RetroDUR initiative.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

9. New managed Therapeutic Drug Classes

- None at this time.

10. Review of Newly-Developed/Revised Clinical Coverage Criteria and/or Preferred Products

- None at this time.

11. General Announcements Mike Ouellette, RPh, GHS/Emdeon

- Selected FDA Safety Alerts
  - Mucinex Fast-MAX Products: Recall - Incorrect Labeling
    Including certain lots of Mucinex Fast-MAX Night Time Cold & Flu; Mucinex Fast-MAX Cold & Sinus; Mucinex Fast-MAX Severe Congestion & Cough and Mucinex Fast-MAX Cold, Flu & Sore Throat
    http://www.fda.gov/Safety/Recalls/ucm444028.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
    - No action required.
  - FDA issues final guidance on the evaluation and labeling of abuse-deterrent opioids
    http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm440713.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
    - No action required.
  - Counterfeit Version of Botox Found in the United States
    http://www.fda.gov/Drugs/DrugSafety/ucm443217.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
    - No action required.
  - FDA Drug Safety Communication: FDA warns of serious slowing of the heart rate when antiarrhythmic drug amiodarone is used with hepatitis C treatments containing sofosbuvir (Harvoni or Sovaldi) in combination with another Direct Acting Antiviral drug
    http://www.fda.gov/Drugs/DrugSafety/ucm439484.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
    - No action required.
  - Amyotrophic Lateral Sclerosis (ALS) Statement
    http://www.fda.gov/Drugs/DrugSafety/ucm443242.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
    - No action required.

13. Adjourn: Meeting adjourned at 8:12 p.m.

Comment [BS1]: I thought the meeting adjourned a bit later than this, around 8:10 pm?

Comment [BMB2]: Stacey is correct. The meeting ended 8:10-8:15

Comment [HN3]: I compromised at 8:12pm